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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,238	12/05/2001	Lawrence A. Shimp	525400-208	8543

7590 06/23/2004  
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EXAMINER

WILLSE, DAVID H

ART UNIT	PAPER NUMBER
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3738

DATE MAILED: 06/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

10/005,238

Applicant(s)

SHIMP ET AL.

Examiner

Dave Willse

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED May 20, 2004, FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY** [check either a) or b)]

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☒ The proposed amendment(s) will not be entered because:
- (a) ☒ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☒ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: See Continuation Sheet.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☐ The a) ☐ affidavit, b) ☐ exhibit, or c) ☐ request for reconsideration has been considered but does NOT place the application in condition for allowance because: \_\_\_\_\_.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☒ will not be entered or b) ☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

Claim(s) rejected: 1-10, 12-14, 18-20, 22, 23, 25-29, 33, 60-63, 72, 73, 80, 86, 87, 114-116 and 127.

Claim(s) withdrawn from consideration: 11, 15-17, 21, 24, 30-32, 34-59, 64-71, 74-79, 81-85, 88-113, 117-126 and 128-138.

8. ☐ The drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.

10. ☐ Other: \_\_\_\_\_



Dave Willse  
Primary Examiner  
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Continuation of 2. NOTE: The added language to claim 114 at lines 5-6 pertaining to the "non-demineralized interior" requires further consideration of the prior art, and the Applicant has not specifically pointed out where such a feature is found in the original disclosure (MPEP 714.02). Although proposed claim 1 appears to distinguish over US 6,200,347 B1, other prior art must be reviewed. Unamended claims 72, 80, and 127 are not allowable for reasons set forth in the final Office action and further explained on the attached pages.

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In regard to present claim 80, Figure 42B (for example) of Anderson et al. illustrates a stacked plurality of planar cortical bone sheets (column 26, lines 23-28) each having interface surfaces (defined by the steps: column 11, lines 1-5) abutting an adjacent sheet and extending transversely the length direction (Figure 42B being a side view) and bores at the interface surfaces with cortical bone pins (column 5, lines 12-13) that can extend in "the height, width, *or length*" direction in the bores (e.g., column 14, lines 34-39; emphasis added; column 28, lines 35-37). The Applicant refers to the Applicant's Figure 46, yet the Applicant's election of July 16, 2003, asserts that claim 80 also reads on the Applicant's Figures 34 and 37. If this is so, then claim 80 is certainly readable on several of the Anderson et al. embodiments.

In regard to instant claim 72, since there need only be one step (e.g., a "step up" or a "step down") in Anderson et al. variants (column 14, lines 6-15), one or the other of the cortical bone portions 132 in Figure 42B would assume the form of an L shape. The Applicant characterizes the claimed invention as involving "a macro recess" (page 7, line 9, of the Applicant's Remarks), but the depth or height of the Anderson et al. steps can be as much as about 3.5 mm (column 14, lines 20-22), which is the same order of magnitude as other implant dimensions.

In regard to Applicant's claim 127 (and proposed claim 114), the Applicant contends that in Andersen et al., "[t]he demineralization is not disclosed as partial" (page 10, lines 8-10, of the Applicant's Remarks). The examiner disagrees: attention is directed to claim 16 of the patent. Moreover, said patent repeatedly states that the two or more bone portions "may optionally be demineralized" (column 27, lines 22-26; column 38, lines 47-50; etc.). The Applicant emphasizes process limitations in current claim 127, but

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the claim is drawn to a spinal implant, not a manufacturing method. That abutting cortical bone surfaces result in an interlocking of respective crystals at the interface, especially after implantation, is evident from the innate function of said crystals as described in the Guyton text referenced in the final Office action, the crystals being "overlapped like bricks keyed to each other in a brick wall" (Guyton: second column of page 941, lines 1-5). It may be that the Applicant discloses a different *process* of making the device, but the burden is on the Applicant to show an unobvious difference in the *end product* (MPEP 2113).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dave Willse whose telephone number is (703) 308-2903. The examiner can normally be reached Monday through Thursday and often on Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.



**Dave Willse**  
**Primary Examiner**  
**Art Unit 3738**